K031691

SEP - 3 2003

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Merit Medical Systems, Inc.
Merit MAK (Mini Access Kit)
ABBREVIATED PREMARKET NOTIFICATION [510(k)]
CONFIDENTIAL
510(k) Summary (per 21 CFR 807.92)

11.0 Premarket Notification [510(k)] Summary of Safety and Effectiveness

Submitter

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095-2416 USA

Establishment Registration Number

1721504

Contact Person(s)

Primary Contact:

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Date Prepared

May 30, 2003

Merit Medical Systems, Inc.
Merit MAK (Mini Access Kit)
ABBREVIATED PREMARKET NOTIFICATION [510(k)]
CONFIDENTIAL

510(k) Summary (per 21 CFR 807.92)

Name of Medical Device	Merit® MAK (Mini Access Kit)
Classification Name:	Vessel Dilator for Percutaneous Catheterization (21 CFR 870.1310)
Common/Usual Name:	Vessel Dilator/Introducer Sheath
Trade/Proprietary Name:	Merit® MAK (Mini Access Kit)

Device Classification

Panel:	Cardiovascular
Device Class:	Class II
Product Code:	74 DRE
Regulation Number:	21 CFR 870.1310

Predicate Device Identification

Device Brand Name	Micropuncture® Introducer Set
Classification Name	Catheter Introducer (21 CFR 870.1340)
Device Class	Class II
Classification Panel Number	870 Cardiovascular Devices
Product Code	DYB
Clearance Status	Preamendment Device
Manufacturer	Cook Incorporated
Registration Number	1820334

Device Description

The Merit® MAK (Mini Access Kit) utilizes a small diameter coaxial introducer/dilator pair and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred.

The Merit® MAK consists of the following components:

- One (1) 4 French or 5 French Coaxial Introducer/Dilator Pair
- One (1) 21 gauge Introducer Needle
- One (1) 0.018" (0.46mm) Guide Wire
  Three versions of guide wires will be offered:
  - Stainless Steel Wire and Tip
  - Stainless Steel Wire with Platinum Tip
  - Nitinol Wire with Platinum Tip

510(k) Summary (per 21 CFR 807.92)

Intended Use

The Merit® MAK (Mini Access Kit) is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.

Summary of Characteristics in Relation to Predicate Device

Does the new device have the same indication statement as the predicate device?
Yes.

Does the new device have the same technological characteristics, e.g., design, materials, etc. as the predicate device?
Yes. The Merit® MAK employs a similar method of operation and design as compared to the predicate device. Both devices consist of a coaxial introducer/dilator pair, introducer needle and guide wires in similar configurations.

Are the descriptive characteristics precise enough to ensure equivalence to the predicate device?
No. Bench testing was conducted on the Merit® MAK in order to ensure device safety and effectiveness for its intended use.

Are performance data available to assess effects of the new device as compared to the predicate device?
Yes. Bench testing was conducted according to international standards and guidance documents as well as in-house protocols.

Does performance data demonstrate equivalence?
Yes. Performance data demonstrates that the Merit® MAK is substantially equivalent to the predicate device and/or met the acceptance criteria as defined in design verification and validation protocols. The risks associated with use of the Merit® MAK were found acceptable when evaluated by FMEA.

Conclusion: "Substantial Equivalence" Determination
The Merit® MAK met all acceptance criteria of the testing performed and, based on CDRH's substantial equivalence decision tree, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2003

Merit Medical Systems, Inc.
c/o Jerrie Hendrickson
Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095-2416

Re: K031691
Merit MAK (Mini Access Kit)
Regulation Number: 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization.
Regulatory Class: Class II
Product Code: DRE
Dated: August 27, 2003
Received: August 28, 2003

Dear Ms. Hendrickson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

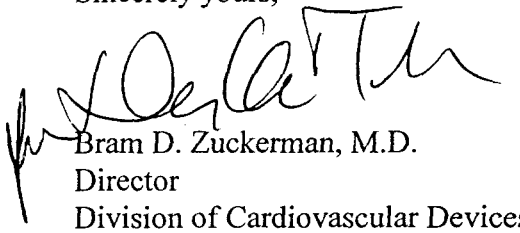
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION(S) FOR USE STATEMENT *

The Merit® MAK (Mini Access Kit) is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.

Signature of 510(k) Submitter: Jerrie Hendrickson

Printed Name of Submitter: Jerrie Hendrickson
Regulatory Affairs Specialist
Merit Medical Systems, Inc.

Date: May 30, 2003

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

(PLEASE DO NOT WRITE BELOW THIS LINE -
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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K031691

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031691

Division Sign-Off
Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use _____